PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent Application of Douglas E. Kligman, *et al.*	:	Group Art Unit 1615
Conf. No.:	7303	:	
Appln. No:	09/131,076	:	Examiner: Susan Tran
Filed:	August 7, 1998	:	
Title:	COMPOSITION AND METHOD OF EFFECTING SUPERFICIAL CHEMICAL SKIN PEELS	:	Attorney Docket No. **10052-1U1**

REQUEST FOR RECONSIDERATION

This is in response to the Office Action dated July 2, 2001 (Paper No. 21) in the above-identified patent application.

Claims 1-14 and 20-22 are presently pending in the application.

At the outset, applicants wish to express their extreme displeasure with the piecemeal examination of this application which has been carried out by the Patent Offi in connection with the invention of the present application. This is the seventh Office Action relating to this invention, including two Office Actions in the abandoned grandparent Application No. 08/597,370, a Written Opinion in the International Application PCT/US97/01919, and four Office Actions in the present application. Each time applicants present arguments or evidence to overcome a prior art rejection, the Examiner or her predecessors have applied different prior art references, despite the fact that none of these references are new.

With respect to the present Office Action, it is noted that the prior art relied upon by the Examiner (Published International Application WO 93/10756 of Blank and U.S. Patent 4,514,385 of Damani et al.) were cited in a European Search Report, which was

submitted to the present Examiner in a Supplemental Information Disclosure Statement filed September 12, 2000, prior to the previous Office Action dated October 3, 2000. The Examiner considered that Supplemental Information Disclosure Statement prior to the Office Action of October 3, 2000, but did not rely upon the prior art cited therein. Only after applicants overcame the improper prior art rejections in the Office Action of October 3, 2000 did the Examiner rely upon the references from the European Search Report in the present Office Action.

Moreover, it is noted that the Blank PCT application is a counterpart of a whole series of U.S. patents of Blank which were actually cited in an Information Disclosure Statement filed in grandparent Application No. 08/597,370 and again in an Information Disclosure Statement filed in the present application on August 7, 1998. Despite the fact that the Blank references have been of record in the grandparent and present application from the outset, not until the present Office Action has the Examiner or her predecessors considered any of the Blank references to be sufficiently relevant to the presently claimed invention to warrant reliance thereon in a rejection of the claims.

In view of the above, it is believed that the Examiner's present rejections are gratuitous and improper. Nevertheless, applicants will respond to the rejections in detail below.

The Examiner has rejected claims 1-6, 11, 12 and 20-22 under 35 U.S.C. 102(b) as anticipated by International Application Publication WO 93/10756 of Blank or alternatively under 35 U.S.C. 103(a) as being unpatentable over Blank. The Examiner contends that Blank teaches a method of regulating wrinkles by topically applying to the skin an effective amount of salicylic acid in ethanol solution where the concentration of salicylic acid in the composition can range from 0.01 to 50% (see pages 2-4 and 6 and claim 2). The Examiner further contends that it would have been obvious that salicylic acid at a concentration of up to 50% is safe and useful for the treatment of the skin. These rejections are respectfully but strenuously traversed for the reasons set forth in detail below.

First of all, the presently claimed invention is a method for effecting a superficial chemical skin peel wherein the solution of salicylic acid is allowed to be present on the surface of the skin for a time sufficient to produce a chemical peel of stratum corneum of the skin. Nowhere in Blank is there any teaching of peeling of the stratum corneum of the skin using Blank's compositions. In fact, in the paragraph bridging pages 1 and 2 of the reference where

Blank describes the prior art, Blank specifically distinguishes his invention from the prior art uses of salicylic acid which generally involved short term treatments in which relatively large doses of the acid were applied sufficient to cause significant irritation and often peeling (see page 1, line 35-page 2, line 7 of Blank).

In contrast, Blank teaches a method for regulating wrinkles and/or atrophy in mammalian skin by chronic treatment of the skin with a safe and effective amount of salicylic acid (page 2, lines 13-15). It is clear from the definitions at page 3, lines 10-27 of Blank that "safe and effective amount" means low enough to avoid serious side effects (page 3, lines 12-13), and "chronic treatment" means continued treatment with the active agent over an extended period of time, preferably at least about three weeks and more preferably about three months to about twenty years (page 3, lines 22-25).

Since the method of the present invention intentionally produces a chemical peel of the stratum corneum of the skin, it cannot be used in chronic treatment. Thus, if the chemical peel method of the present invention were administered chronically, as suggested by Blank, it would result in serious skin injury to the patient, since each application of the solution of the present invention is intended to strip a number of layers from the superficial epidermis. Hence, the present invention is intended to be used as a single application or at most once every two weeks for three or four applications, preferably spaced one month apart.

It is true that Blank states that the topical pharmaceutical compositions of his invention may contain from about 0.01% to 50% of the active compound (salicylic acid). One skilled in the art would recognize that this range is at best prophetic, since salicylic acid is not even soluble in ethanol or similar solvents at concentrations much above 30%. Moreover, it is clear that the upper end of this range is not suitable for Blank's invention, since in most cases, such concentrations would not be "safe and effective amounts" for "chronic treatment." This is particularly the case where, as in the present invention, the solution of the salicylic acid is in a volatile liquid solvent, such as ethanol. Hence, it is not surprising that no specific example of Blank contains more than 2 wt % salicylic acid, and even then the compositions contain water and various emollients and other ingredients to allow for safe and effective chronic treatment (see Examples I-V at pages 22-26 of Blank). Such concentrations are far below the minimum 15 wt % salicylic acid used in the method of the present invention in order to produce a chemical skin peel.

In sum, there is no teaching in Blank of producing a chemical skin peel, and in fact Blank teaches away from the short term, high concentration uses of salicylic acid which caused significant irritation and peeling. The high concentrations of salicylic acid included in the broad ranges of Blank are impossible to be used in a volatile liquid solvent, since such concentrations would violate Blank's requirements for "safe and effective amounts" and a "chronic treatment." Accordingly, Blank fails to anticipate or render obvious the presently claimed invention and instead teaches away from it. Therefore, reconsideration and withdrawal of the rejections are respectfully requested.

The Examiner has rejected claims 1, 13 and 14 under 35 U.S.C. 103(a) as being unpatentable over Blank in view of U.S. Patent 4,514,385 of Damani et al. The Examiner acknowledges that Blank is silent as to a teaching of salicylic acid for the treatment of acne. However, the Examiner contends that Damani et al. teach a composition comprising about 0.1 to 25% salicylic acid for the treatment of acne (column 2, line 49-column 3, line 2). The Examiner concludes that it would have been obvious to one skilled in the art to modify Blank's composition for the treatment of skin acne in view of the teaching of Damani et al. The Examiner reasons that the modification is to obtain a composition up to 50% salicylic acid that is safe and useful for the treatment of skin wrinkles, acne or other skin related conditions. This rejection is also respectfully but strenuously traversed.

First, the Examiner's reasoning for the combination of Blank and Damani et al. is not understood. No basis can be seen for the Examiner's statement that skin wrinkles and acne are related skin conditions. Moreover, it is not seen how up to 50% salicylic acid is taught by Damani et al. to be safe or useful. In fact, the specific examples of Damani et al. use only 4% and 7.5% salicylic acid, but then only in combination with benzoyl peroxide and only in an aqueous formulation rather than a volatile solvent.

Thus, benzoyl peroxide is a well known anti-acne product in the form of a gel with the carrier preferably being a carboxy vinyl polymer resin. It is clear from Damani et al. that the preparations of that patent are not solutions. That is, if benzoyl peroxide and salicylic acid were used in a solution, they would react in such a manner that the benzoyl peroxide would rapidly oxidize the salicylic acid, rendering it much less effective. Therefore, the general insolubility of benzoyl peroxide and salicylic acid in water enables these substances to be dispersed in the aqueous gel without significant reaction (column 2, lines 40-43).

Further, like Blank, the compositions of Damani et al. are intended for persistent or chronic application, preferably one or more times daily (see column 4, lines 50-52). It is not intended, as is the present invention, for a single application or several widely spaced applications to produce a chemical peel of the stratum corneum.

In sum, neither Blank nor Damani et al. teaches a chemical skin peel method. Therefore, even if the combination of Blank and Damani et al. were proper, which applicants do not agree, the combination still fails to teach or suggest the presently claimed invention. Accordingly, the rejection is improper and should be withdrawn.

In view of the above remarks, it is submitted that all of the claims in the application patentably distinguish over the prior art of record. Reconsideration and an early Notice of Allowance are respectfully solicited.

Respectfully submitted,

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November 2, 2001 By: _____

(Date)

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